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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 526, 556, and 558

[Docket No. FDA-2021-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditional new animal drug applications (cNADAs) during January, February, and March 2021. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and conditional approval actions for cNADAs during January, February, and March 2021, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National

Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.

FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During January, February, and March 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 8, 2021	141-336	ECO LLC, 344 Nassau St. Princeton, NJ 08540	AIVLOSIN (62.5% w/w tylvalosin as tylvalosin tartrate) Water Soluble Granules	Swine	Supplemental approval for the addition of *Mycoplasma hyopneumoniae* to the list of pathogens for the control of swine respiratory disease indication	FOI Summary
January 11, 2021	141-526	Anivive Lifesciences, Inc. 3250 Airflite Way, suite 400 Long Beach, CA 90807	LAVERDIA-CA1 (verdinexor tablets)	Dogs	Conditional approval for the treatment of lymphoma in dogs	FOI Summary
January 12, 2021	200-675	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	Ractopamine hydrochloride and monensin Type B and Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 141-225	FOI Summary
January 12, 2021	200-676	Do.	Ractopamine hydrochloride, monensin, and tylosin phosphate Type B and Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 141-224	FOI Summary
January 12, 2021	200-677	Do.	Ractopamine hydrochloride, monensin, and melengestrol acetate Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 141-234	FOI Summary
January 12, 2021	200-678	Do.	Ractopamine hydrochloride, monensin, tylosin phosphate, and melengestrol acetate Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 141-233	FOI Summary
January 14, 2021	141-544	Pegasus Laboratories, Inc. 8809 Ely Rd. Pensacola, FL 32514	KBROVET-CA1 (potassium bromide chewable tablets) Chewable Tablet	Dogs	Conditional approval for the control of seizures associated with idiopathic epilepsy in dogs	FOI Summary
January 15, 2021	141-539	Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511	THYROKARE (levothyroxine sodium tablets)	Dogs	Original approval for replacement therapy for diminished thyroid function in dogs	FOI Summary
February 1, 2021	200-683	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	Melengestrol acetate and monensin Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 125-476	FOI Summary
February 1, 2021	200-684	Do.	Ractopamine hydrochloride, monensin, and melengestrol acetate Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 141-234	FOI Summary

February 1, 2021	200-685	Do.	Melengestrol acetate, monensin, and tylosin phosphate Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 138-870	FOI Summary
February 1, 2021	200-686	Do.	Monensin, ractopamine hydrochloride, tylosin phosphate, and melengestrol acetate Type C medicated feeds	Cattle	Original approval as a generic copy of NADA 141-233	FOI Summary
February 8, 2021	200-466	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215	SPARMECTIN Plus Clorsulon (ivermectin and clorsulon) Injection	Cattle	Supplemental approval reducing preslaughter withdrawal period to 21 days	FOI Summary
February 16, 2021	200-506	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	ANIMEC PLUS (ivermectin and clorsulon) Injection	Cattle	Original approval as a generic copy of NADA 140-833	FOI Summary
February 18, 2021	200-657	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland	MACROSYN (tulathromycin injection) Injectable Solution	Cattle	Original approval as a generic copy of NADA 141-244	FOI Summary
February 18, 2021	200-666	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	INCREXXA (tulathromycin injection) Injectable Solution	Cattle	Original approval as a generic copy of NADA 141-244	FOI Summary
February 26, 2021	141-540	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	PENNITRACIN MD (bacitracin Type A medicated article) and COBAN (monensin Type A medicated article) to be used in the manufacture of Type C medicated feeds	Turkeys	Original approval for the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys	FOI Summary
March 11, 2021	200-699	Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045	Dexmedetomidine Hydrochloride Injection (dexmedetomidine hydrochloride)	Dogs and cats	Original approval as a generic copy of NADA 141-267	FOI Summary

March 15, 2021	141-530	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	MGA (melengestrol acetate Type A medicated article) and AUREOMYCIN (chlortetracycline Type A medicated article) to be used in the manufacture of Type C medicated feeds	Cattle	Original approval for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat) in replacement dairy and beef heifers, or growing beef heifers fed in confinement for slaughter receiving medicated feed containing chlortetracycline for the treatment of bacterial enteritis or pneumonia, control of bacterial pneumonia associated with shipping fever complex, reduction of incidence of liver abscesses, and control of active infection of anaplasmosis	FOI Summary
March 19, 2021	141-531	Do.	MGA (melengestrol acetate Type A medicated article), AUREOMYCIN (chlortetracycline Type A medicated article), and BOVATEC (lasalocid Type A medicated article) to be used in the manufacture of Type C medicated feeds	Cattle	Original approval for suppression of estrus (heat) in replacement dairy and beef heifers, or growing beef heifers fed in confinement for slaughter receiving medicated feed containing chlortetracycline for the treatment of bacterial enteritis or pneumonia, control of bacterial pneumonia associated with shipping fever complex, or control of active infection of anaplasmosis; and lasalocid for control of coccidiosis, increased rate of weight gain, and improved feed efficiency	FOI Summary
March 22, 2021	200-625	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland	KETOMED (ketoprofen) Sterile Solution	Horses	Original approval as a generic copy of NADA 140-269	FOI Summary
March 24, 2021	132-872	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	SAFE-GUARD (fenbendazole) Paste 10%	Cattle	Supplemental approval providing for tolerances, a tissue withdrawal period, and a milk discard time in accordance with a repartitioning of the acceptable daily intake; and the addition of indications for fourth-stage larvae of certain endoparasites	FOI Summary

II. Changes of Sponsor

The sponsors of the following approved applications have informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor:

File No.	Product name	Transferring sponsor	New sponsor	21 CFR Section
141-175	CAPSTAR (nitenpyram) Tablets	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138	520.1510
141-120	CLOMICALM (clomipramine hydrochloride) Tablets	Do.	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161	520.455
141-474	ITRAFUNGOL (itraconazole oral solution)	Do.	Do.	520.1189
065-081	GO-DRY (penicillin G procaine) Intramammary Infusion	G. C. Hanford Mfg. Co., P.O. Box 1017, Syracuse, NY 13201	HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652	526.1696
200-335	Ampicillin Sodium Powder for Injection	Do.	Do.	522.90c
200-372	HAN-PEN (penicillin G potassium) Soluble Powder	Do.	Do.	520.1696a
065-071	Chlortetracycline (chlortetracycline hydrochloride) Soluble Powder	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	520.441
065-440	CHLORONEX (chlortetracycline hydrochloride) Soluble Powder	Do.	Do	Do.
200-441	A-MYCIN (chlortetracycline hydrochloride) Soluble Powder	Do.	Do	Do.
200-528	SAVALAN 60 (salinomycin sodium) Type A medicated article	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	558.550
200-237	Isoflurane, U.S.P.	Piramal Enterprises Ltd., Ananta, Agastya Corporate Park, Opp Fire Brigade, Kamani Junction, LBS Mag Kurla (West), Mumbai, 400070, India	Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India	N/A

Following these changes of sponsorship, G. C. Hanford Manufacturing Co. and Piramal Enterprises Ltd. are no longer the sponsor of an approved application. Accordingly, the regulations in 21 CFR 510.600(c) are being amended to reflect these changes.

III. Technical Amendments

FDA is making the following amendments to improve the accuracy, consistency, and readability of the animal drug regulations:

- 21 CFR 510.600 is amended by revising the entries for Cronus Pharma Specialities India Private Ltd. to reflect the correct address for the firm.
- 21 CFR 520.2090 is amended to reflect the current approved indications for use for sarolaner, moxidectin, and pyrantel tablets.
- 21 CFR 522.970 is amended to reflect the approved species for a flunixin injectable solution.
- 21 CFR 558.76 for use of bacitracin methylenedisalicylate in medicated feed is amended to reflect a current tabular format organized by species.
- 21 CFR 558.128 is amended to reflect sponsors of combination medicated feeds containing chlortetracycline for which there is no preslaughter withdrawal period.
- 21 CFR 558.355 for use of monensin in medicated feeds is amended to reflect the sponsor of an approved generic product and to remove a redundant condition of use.

IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires *Federal Register* publication of "notice[s]… effective as a regulation," of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a "rule of particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 526

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR parts 510, 516, 520, 522, 526, 556, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600:

a. In the table in paragraph (c)(1):

i. Add in alphabetical order an entry for “Anivive Lifesciences, Inc.”;

ii. Revise the entry for “Cronus Pharma Specialities India Private Ltd.”;

iii. Remove the entries for “G. C. Hanford Manufacturing Co.” and “Piramal Enterprises Ltd.”; and

iv. Add in alphabetical order an entry for “Piramal Pharma Ltd.”; and

b. In the table in paragraph (c)(2):

i. Remove the entry for “010515”;

ii. Revise the entries for “065085” and “069043”; and

iii. Add in numerical order an entry for “086121”.

The revisions and additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Anivive Lifesciences, Inc., 3250 Airflite Way, suite 400, Long Beach, CA 90807	086121
* * * * * * *	
Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India	069043
* * * * * * *	
Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India	065085
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
065085	Piramal Pharma Ltd., Ground Floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra, 400070, India
* * * * * * *	
069043	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India
* * * * * * *	
086121	Anivive Lifesciences, Inc., 3250 Airflite Way, suite 400, Long Beach, CA 90807

* * * * * * *

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc, 360ccc-2, 371.

4. Add § 516.1858 to subpart E to read as follows:

§ 516.1858 Potassium bromide.

(a) *Specifications*. Each chewable tablet contains 250 or 500 milligrams (mg) potassium bromide.

(b) *Sponsor*. See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Amount*. Administer 25 to 68 mg per kilogram (11 to 31 mg per pound) of body weight once daily. The dosage can be divided and should be adjusted to clinical response.

(2) *Indications for use*. For the control of seizures associated with idiopathic epilepsy in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

5. Add § 516.2980 to subpart E to read as follows:

§ 516.2980 Verdinexor.

(a) *Specifications*. Each tablet contains 2.5, 10, or 50 milligrams (mg) verdinexor.

(b) *Sponsor*. See No. 086121 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Amount*. Administer verdinexor tablets orally at an initial dose of 1.25 mg per kilogram (mg/kg) of body weight twice per week with at least 72 hours between doses. If tolerated after 2 weeks, increase the dose to 1.5 mg/kg twice per week with at least 72 hours between doses.

(2) *Indications for use*. For the treatment of lymphoma in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

7. In § 520.441, revise paragraph (b)(1) to read as follows:

§ 520.441 Chlortetracycline powder.

* * * * *

(b) * * *

(1) Nos. 000010, 054771, and 069254 for use as in paragraph (d) of this section.

* * * * *

8. In § 520.455, revise the section heading and paragraph (b) to read as follows:

§ 520. 455 Clomipramine.

* * * * *

(b) *Sponsors.* See Nos. 051311 and 086039 in § 510.600(c) of this chapter.

* * * * *

9. In § 520.905c, revise paragraph (e)(2) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(e) * * *

(2) *Beef and dairy cattle*--(i) *Amount*. Administer orally 2.3 mg/lb (5 mg/kg) body weight.

(ii) *Indications for use.* For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole

worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

(iii) *Limitations*. Milk taken during treatment and for 96 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.

10. In § 520.1189, revise paragraph (b) to read as follows:

§ 520.1189 Itraconazole.

* * * * *

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

* * * * *

11. In § 520.1248, revise paragraphs (b) and (c)(1) to read as follows:

§ 520.1248 Levothyroxine.

* * * * *

(b) *Sponsors.* See Nos. 059051 and 061690 in § 510.600(c) of this chapter.

(c) * * *

(1) *Amount.* Administer by mouth as follows:

(i) No. 061690: 0.1 mg/10 pounds (lb) body weight (0.022 mg/kilogram (kg)) as a single dose every 24 hours or as a divided dose every 12 hours.

(ii) No. 059051: 0.1 mg/10 lb (0.01 mg/lb, 0.022 mg/kg) body weight twice daily.

* * * * *

12. In § 520.1510, revise paragraph (b)(1) to read as follows:

§ 520. 1510 Nitenpyram.

* * * * *

(b) * * *

(1) No. 021091 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), and (d)(2) of this section.

* * * * *

13. In § 520.1696a, revise paragraph (b) to read as follows:

§ 520.1696a Penicillin G powder.

* * * * *

(b) *Sponsors.* See Nos. 016592, 042791, 054771, 061133, and 076475 in § 510.600(c) of this chapter.

* * * * *

14. In § 520.2090, revise paragraph (c)(2) to read as follows:

§ 520.2090 Sarolaner, moxidectin, and pyrantel.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater.

* * * * *

15. In § 520.2645, revise paragraph (d)(2) to read as follows:

§ 520.2645 Tylvalosin.

* * * * *

(d) * * *

(2) *Indications for use*. For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine intended for slaughter in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica*, *Haemophilus parasuis, Pasteurella multocida*, *Streptococcus suis,* and *Mycoplasma hyopneumoniae* in groups of swine intended for slaughter in buildings experiencing an outbreak of SRD.

* * * * *

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

16. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

17. In § 522.90c, revise paragraph (b) to read as follows:

§ 522.90c Ampicillin sodium.

* * * * *

(b) See Nos. 042791 and 054771 in § 510.600(c) of this chapter.

* * * * *

18. In § 522.558, revise paragraphs (b)(1) and to read as follows:

§ 522.558 Dexmedetomidine.

* * * * *

(b) * * *

(1) Nos. 026637 and 059399 for use of product described in paragraph (a)(2) of this section.

* * * * *

19. In § 522.970, revise paragraph (b)(1) and add paragraph (b)(3) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See Nos. 000061, 055529, 058198, and 061133 for use as in paragraph (e) of this section.

* * * * *

(3) See No. 016592 for use as in paragraphs (e)(1) and (e)(2) of this section.

* * * * *

20. In § 522.1193, revise paragraphs (b) and (e)(2) and (3) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(b) *Sponsors*. See Nos. 000010, 055529, 058005, 061133, and 061651 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(2) *Indications for use*. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*; lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); cattle grubs (parasitic stages) (*Hypoderma bovis, H. lineatum*); sucking lice (*Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*); mange mites (cattle scab) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*); and for control of infections of

D. viviparus and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* Do not treat cattle within 21 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

21. In § 522.1225, revise paragraph (b) to read as follows:

§ 522.1225 Ketoprofen.

* * * * *

(b) *Sponsors*. See Nos. 054771 and 061133 in § 510.600(c) of this chapter.

* * * * *

22. In § 522.1696a, revise paragraph (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Not for use within 30 days of slaughter. For No. 016592: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

23. In § 522.2630, revise paragraphs (b) and (d)(1)(iii)(A) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 054771, 058198, and 061133 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

PART 526--INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

24. The authority citation for part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

25. In § 526.1696, revise paragraph (b) to read as follows:

§ 526.1696 Penicillin G procaine.

* * * * *

(b) See Nos. 042791 and 061133 in § 510.600(c) of this chapter.

* * * * *

PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

26. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

27. In § 556.275:

a. Revise paragraph (b)(1)(ii);

b. Remove paragraph (b)(1)(iii); and

c. Remove and reserve paragraphs (b)(3)(ii), (b)(4)(ii), and (b)(5)(ii).

The revision reads as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(1) * * *

(ii) Milk: 0.22 ppm fenbendazole sulfoxide (marker residue).

* * * * *

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

28. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

29. In § 558.76:

a. Revise paragraphs (a)(1) and (2) and (d)(1);

b. Redesignate paragraph (d)(2) as paragraph (d)(6); and

c. Add new paragraph (d)(2) and paragraphs (d)(3) through (5).

The revisions and additions read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

(a) * * *

(1) Type A medicated articles containing feed grade bacitracin methylenedisalicylate equivalent to 10, 25, 30, 40, 50, 60, or 75 grams bacitracin per pound.

(2) Type A medicated article containing feed grade bacitracin methylenedisalicylate equivalent to 50 grams bacitracin per pound.

* * * * *

(d) * * *

(1) *Chickens*--

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor

(i) 4 to 50	Broiler and replacement chickens: For increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration.	054771 069254
(ii) 10 to 25	Laying hens: For increased egg production and improved feed efficiency	Feed continuously as sole ration for the first 7 months of egg production.	054771
(iii) 50	Broiler and replacement chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration.	054771
(iv) 100 to 200	Broiler and replacement chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin	Feed continuously as sole ration. Start at first clinical signs of disease. Vary dosage based on severity of infection. Administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 grams/ton).	054771

(2) *Turkeys*--

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	Growing turkeys: For increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration.	054771 069254
(ii) 200	Growing turkeys: As an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate	Feed continuously as the sole ration.	054771

(3) *Swine*--

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 30	Growing and finishing swine: For increased rate of weight gain and improved feed efficiency		054771
(ii) 250	Growing and finishing swine: For control of swine dysentery (bloody scours) associated with *Brachyspira hyodysenteriae* in pigs up to 250 lbs body weight	Feed as the sole ration. Feed 250 grams per ton of complete feed on premises with a history of swine dysentery, but where signs of the disease have not yet occurred or following an approved treatment of the disease condition. Diagnosis should be confirmed by a veterinarian a when results are not satisfactory.	054771
(iii) 250	Pregnant sows: For control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets	As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.	054771

(4) *Cattle*--

Bacitracin amount	Indications for use	Limitations	Sponsor
(i) 70 mg per head per day	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses	Administer continuously throughout the feeding period.	054771 069254
(ii) 250 mg per head per day	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	054771 069254

(5) *Game birds*--

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50	Growing pheasants: For increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration.	054771 069254
(ii) 5 to 20	Growing quail: For increased rate of weight gain and improved feed efficiency in quail not over 5 weeks of age	Feed continuously as sole ration to quail not over 5 weeks of age.	054771 069254
(iii) 200	Growing quail: For the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate	Feed continuously as the sole ration.	054771

* * * * *

30. In § 558.128, revise paragraphs (d)(4) and (e)(4) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(d) * * *

(4) Manufacture for use in free-choice feeds as in paragraph (e)(4)(vi) of this section must conform to § 510.455 of this chapter.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) to provide 70 mg/head/day		Growing cattle (over 400 lb): For reduction of liver condemnation due to liver abscesses	Feed to provide chlortetracycline at the rate of 70 mg per animal daily. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 066104 069254
(ii) 5.83 to 14 g/ton to provide 70 mg/head/day	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day	Growing beef heifers fed in confinement for slaughter (over 400 lb): For reduction of the incidence of liver abscesses, increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing 5.83 to 14 g/ton chlortetracycline. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) to provide 0.5 mg/lb of body weight daily		Beef cattle (over 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline	Feed to provide chlortetracycline at the rate of 0.5 mg per pound of body weight daily in beef cattle under 700 pounds. Withdraw 48 hours prior to slaughter. To sponsor Nos. 054771 and 069254: Zero withdrawal time.	054771 066104 069254
(iv) 33.33 to 50 g/ton to provide 0.5 mg/lb of body weight per day	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day	Replacement beef heifers over 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 33.33 to 50 g/ton chlortetracycline. Feeding a Type C top-dress medicated feed containing melengestrol acetate shall not exceed 24 days. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(v) 25 to 1,100 g/ton to provide 0.5 mg/lb of body weight daily	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) over 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis 0.5 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(vi) 25 to 1,100 g/ton to provide 0.5 mg/lb of body weight daily	Lasalocid, 30 to 600; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate	Replacement beef heifers on pasture over 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 1,100 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 0.5 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) to provide 0.5 to 2.0 mg/lb of body weight daily		Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section.	054771 069254
(viii) to provide 10 mg/lb of body weight daily		Calves, beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 days. To sponsor No. 054771 (NADAs 048-761 and 046-699) and to sponsor No. 069254 (ANADA 200-510): may be mixed in the cattle's daily ration or administered as a top-dress. In feed including milk replacers withdraw 10 days prior to slaughter. To sponsor Nos. 054771 and 069254:	054771 066104 069254

			zero withdrawal time. See paragraph (d)(3) of this section.	
(ix) to provide 10 mg/lb of body weight daily		Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *Escherichia coli* susceptible to chlortetracycline	A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 066104 069254
(x) to provide 10 mg/lb of body weight daily	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xi) to provide 10 mg/lb of body weight daily	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xii) 500 to 2,000 to provide 10 mg/lb of body weight daily	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 100 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254

(xiii) to provide 10 mg/lb of body weight daily	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xiv) 500 to 4,000 to provide 10 mg/lb of body weight daily	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See §558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xv) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily	Lasalocid, 30 to 600: melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate	Replacement dairy heifers on pasture less than 20 months of age and replacement beef heifers on pasture: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 10 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No.	054771

			054771 in § 510.600(c) of this chapter.	
(xvi) 500 to 4,000 g/ton		Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline	Hand feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 046-699: 24-hour withdrawal period. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: Zero withdrawal period.	054771 069254
(xvii) 500 to 4,000 g/ton	Decoquinate, 12.9 to 90.8	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xviii) 500 to 4,000 to provide 10 mg per pound of body weight	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day	Growing beef heifers fed in confinement for slaughter: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton chlortetracycline for not more than 5 days. After competing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xix) 500 to 4,000 to provide 10 mg per pound of body weight	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day	Replacement dairy heifers less than 20 months of age and replacement beef heifers: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, and for suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton chlortetracycline for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days. Use in dairy heifers less	054771

			than 20 months of age may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	
(xx) 4,000 to 20,000 g/ton		Calves, beef and nonlactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline	Administer as a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 069254
(xxi) 4,000 to 20,000 g/ton	Decoquinate, 90.8 to 535.7	Calves, beef and non-lactating dairy cattle: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Feed at a rate of 1g chlortetracycline per 100 lb body weight/day and 22.7 mg decoquinate per 100 lb of body weight/day for not more than 5 days. When it is fully consumed, resume feeding 22.7 mg decoquinate per 100 lb of body weight/day for a total of 28 days to prevent coccidiosis. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Decoquinate as provided by No. 054771 in §510.600(c) of this chapter.	054771 069254
(xxii) 4,000 to 20,000 g/ton to provide 10 mg/lb of body weight per day	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day	Growing beef heifers fed in confinement for slaughter: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxiii) 4,000 to 20,000 g/ton to provide 10 mg/lb of body weight per day	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day	Replacement dairy heifers less than 20 months of age and replacement beef heifers: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms	Top dress 0.5 to 2 pounds of this medicated feed containing both drugs onto or mix at feeding with a non-medicated feed for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-	054771

		susceptible to chlortetracycline, and for suppression of estrus (heat)	dress medicated feed containing melengestrol acetate alone for a total time not exceeding 24 days. Use in dairy heifers less than 20 months of age may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	
(xxiv) to provide 350 mg/head/day		Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline	Feed to provide chlortetracycline at the rate of 350 mg per animal daily. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Withdrawal periods: To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048-761 and No. 069254 under NADA 138-935 and ANADA 200-510: Zero withdrawal period.	054771 066104 069254
(xxv) to provide 350 mg/head/day		Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline	Feed to provide chlortetracycline at the rate of 350 mg per animal daily. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Withdrawal periods: To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048-761 and No. 069254 under NADA 138-935 and ANADA 200-510: Zero withdrawal period.	054771 066104 069254
(xxvi) 50 to 350 g/ton to provide 350 mg/head/day	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day	Replacement beef heifers under 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed or mixed at feeding with the Type C medicated feed containing 50 to 350 g/ton chlortetracycline for up to 24 days of feeding. Do not exceed 24 days of feeding. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxvii) 20 to 350 g/ton		Beef cattle and replacement dairy heifers: For control of	Feed to provide chlortetracycline at the rate of 350 mg per head per day.	054771 069254

		bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline	This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: Zero withdrawal period.	
(xxviii) 20 to 350 g/ton to provide 350 mg/head/day	Melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg melengestrol acetate per head per day	Growing beef heifers fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with the Type C medicated feed containing 20 to 350 g/ton chlortetracycline. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxix) 20 to 350 g/ton to provide 350 mg/head/day	Melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg melengestrol acetate per head per day	Replacement dairy heifers less than 20 months of age and replacement beef heifers: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and suppression of estrus (heat)	Melengestrol acetate Type C top-dress medicated feed must be top dressed or mixed at feeding with the Type C medicated feed containing 20 to 350 g/ton chlortetracycline. Use in dairy heifers less than 20 months of age may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Chlortetracycline and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxx) to provide 350 mg/head/day	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for increased rate of weight and improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxxi) to provide 350 mg/head/day	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter.	054771

			Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	
(xxxii) 25 to 42.2 g/ton to provide 350 mg/head/day	Lasalocid, 25 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxiii) 25 to 42.2 g/ton to provide 350 mg/head/day	Lasalocid, 25 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxiv) 25 to 100 g/ton to provide 350 mg/head/day	Lasalocid, 10 to 30	Cattle under 700 pounds fed in confinement for slaughter: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxv) 25 to 100 g/ton to provide 350 mg/head/day	Lasalocid, 10 to 30	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg lasalocid per head daily. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for	054771 069254

			veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	
(xxxvi) 25 to 700 to provide 350 g/head/day	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xxxvii) 25 to 700 g/ton to provide 350 mg/head/day	Lasalocid, 30 to 600; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate	Replacement beef heifers on pasture: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 700 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xxxviii) 25 to 700 to provide 350 mg/head/day	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, beef replacement heifers) under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis at a rate of 350 mg chlortetracycline and not less than 60 mg nor more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See	054771 069254

			§ 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	
(xxxix) 25 to 700 g/ton to provide 350 mg/head/day	Lasalocid, 30 to 600; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate	Replacement beef heifers on pasture under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, increased rate of weight gain, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 700 g/ton of chlortetracycline and 30 to 600 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 pound of feed. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xl) 25 to 2,800 to provide 350 mg/head/day	Lasalocid, 30 to 181.8	Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Chlortetracycline and lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xli) 25 to 2,80 g/ton to provide 350 mg/head/day	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate	Growing beef heifers fed in confinement for slaughter under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(xlii) 25 to 2,800 to provide 350 mg/head/day	Lasalocid, 30 to 181.8	Beef cattle weighing up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xliii) 25 to 2,800 g/ton to provide 350 mg/head/day	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate	Growing beef heifers fed in confinement for slaughter up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xliv) 25 to 2,800 g/ton to provide 350 mg/head/day	Lasalocid, 30 to 181.8; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate	Replacement beef heifers up to 800 pounds: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 25 to 2,800 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 350 mg chlortetracycline per head daily and 1 mg lasalocid per 2.2 lb. of body weight daily with a maximum of 360 mg lasalocid per head per day. Do not exceed 24 days of feeding. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(xlv) 500 to 4,000 to provide 10 mg/head/day	Lasalocid, 30 to 181.8	Cattle weighing up to 800 pounds: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*	Hand feed continuously for not more than 5 days at a rate of 10 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 069254
(xlvi) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily	Lasalocid, 30 to 181.8; melengestrol acetate, 0.25 to 2 g/ton to provide 0.25 to 0.5 mg/head/day melengestrol acetate	Growing beef heifers fed in confinement for slaughter up to 800 pounds: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii,* increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 10 mg chlortetracycline per lb of body weight per day and 1 mg lasalocid per 2.2 lb of body weight per day with a maximum of 360 mg lasalocid per head per day for not more than 5 days of feeding. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(xlvii) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily	Lasalocid, 30 to 181.8; melengestrol acetate, 0.5 to 2 g/ton to provide 0.5 mg/head/day melengestrol acetate	Replacement dairy heifers up to 800 pounds and less than 20 months of age and replacement beef heifers up to 800 pounds: For the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and suppression of estrus (heat)	The melengestrol acetate Type C top-dress medicated feed must be top dressed onto or mixed at feeding with a Type C medicated feed containing 500 to 4,000 g/ton of chlortetracycline and 30 to 181.8 g/ton lasalocid to provide 10 mg chlortetracycline per lb of body weight per day and 1 mg lasalocid per 2.2 lb of body weight per day with a maximum of 360 mg lasalocid per head per day for not more than 5 days. After completing feeding of this combination, continue feeding a Type C top-dress medicated feed containing melengestrol acetate alone. See § 558.311(d) of this chapter. Chlortetracycline, lasalocid, and melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771

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31. In § 558.342, revise paragraph (e)(1)(iv) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
		* * * * * * *		
(iv) 0.25 to 0.5	Monensin, 10 to 40	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day. See § 558.355(d) of this chapter. Monensin as provided by No. 016592 or 058198; melengestrol acetate as provided by No. 016952,	016592 045771 058198

			054771, or 058198 in § 510.600(c) of this chapter.	
		* * * * * * *		

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32. In § 558.355, revise paragraphs (b)(2), (f)(2)(ii), (f)(3), and (f)(4)(i) and (ii), remove paragraph (f)(4)(v), redesignate paragraph (f)(4)(vi) as paragraph (f)(4)(v) and revise it, and revise paragraphs (f)(6)(i) and (f)(7)(viii)

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(b) * * *

(2) No. 016592 for use of a Type A medicated article containing 90.7 grams monensin, USP, per pound as in paragraphs (f)(3), (f)(4)(v), and (f)(6) of this section.

* * * * *

(f) * * *

(2) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
		* * * * * * *		
(ii) 54 to 90	Bacitracin methylenedisalicylate, 4 to 50	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. The optimum level depends upon the severity of coccidiosis exposure. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylenedisalicylate as provided by No. 054771 or	058198 069254

			069254 in § 510.600(c) of this chapter.	

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(3) * * *

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 5 to 40	Growing beef steers and heifers fed in confinement for slaughter: For improved feed efficiency	Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day). See special labeling considerations in paragraph (d) of this section.	016592 058198
(ii) 10 to 40	Growing beef steers and heifers fed in confinement for slaughter: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day. See special labeling considerations in paragraph (d) of this section.	016592 058198
(iii) 10 to 200	Calves excluding veal calves: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day. See special labeling considerations in paragraph (d) of this section.	016592 058198
(iv) 11 to 22	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)	Feed continuously to dry and lactating dairy cows in a total mixed ration (“complete feed”). See special labeling considerations in paragraph (d) of this section.	016592 058198
(v) 11 to 400	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)	Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section.	016592 058198
(vi) 15 to 400	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) or in a dry lot and replacement beef and dairy heifers: For increased rate of weight gain, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed. See special labeling considerations in paragraph (d) of this section.	016592 058198
(vii) 25 to 400	Beef cows: For improved feed efficiency when receiving supplemental feed, and for the prevention and control of	Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams	016592 058198

	coccidiosis due to *Eimeria bovis* and *E. zuernii*	monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day in not less than 1 pound of feed. See special labeling considerations in paragraph (d) of this section.	

(4) * * *

Monensin amount	Indications for use	Limitations	Sponsor
(i) 150 milligrams per pound of protein-mineral block (0.033%)	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) and replacement beef heifers on pasture: For increased rate of weight gain, and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle which may require supplemental feed	Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. See paragraph (d)(10)(i) of this section.	012286
(ii) 175 milligrams per pound of protein-mineral block (0.038%)	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter): For increased rate of weight gain	Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. See paragraph (d)(10)(i) of this section.	017800

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(v) 1,620 grams per ton of mineral granules as specified in paragraph (f)(4)(v)(A) of this section	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) or in a dry lot and replacement beef and dairy heifers: For increased rate of weight gain, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement.	016592 058198

(A) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International Feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082
Sodium chloride (salt)	24.37	6-04-152
Dried cane molasses	20.0	4-04-695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6-02-632

Cane molasses	3.0	4-04-696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix[1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

[1] Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

(B) [Reserved]

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(6) * * *

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 20	Goats maintained in confinement: For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae*	Feed continuously. Do not feed to lactating goats. See paragraph (d)(11) of this section for provisions for monensin liquid Type C goat feeds.	016592 058198
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(7) * * *

(viii) Ractopamine as in §558.500.

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33. In § 558.500, revise paragraphs (e)(2)(ii), (iv), (v), and (vii) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(ii) 8.2 to 24.6 to provide 70 to 430 mg/head/day	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight,	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and prevention and control of coccidiosis due to	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of	016592 054771 058198

	depending on severity of coccidiosis challenge, up to 480 mg/head/day.	*Eimeria bovis* and *E. zuernii* during the last 28 to 42 days on feed.	this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	
* * * * * * *				
(iv) 9.8 to 24.6 to provide 90 to 430 mg/head/day	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(v) 9.8 to 24.6 to provide 90 to 430 mg/head/day	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii,* and suppression of estrus (heat) during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in §§ 558.342(d) and 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198; melengestrol acetate as provided by No. 016592, 054771 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
* * * * * * *				
(vii) Not to exceed 800; to provide 70 to 400 mg/head/day	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 28 to 42 days on feed.	Top dress ractopamine at a minimum of 1.0 lb/head/day of medicated feed continuously during the last 28 to 42 days on feed. Not for animals intended for breeding. See special labeling considerations in § 558.355(d) of this chapter. Ractopamine as provided by No. 016592, 054771, or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
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34. In § 558. 550, revise paragraphs (a), (b), (e)(1)(i), and (e)(2)(i) to read as follows:

§ 558. 550 Salinomycin.

(a) *Specifications.* Type A medicated articles containing 30 or 60 grams of salinomycin sodium activity per pound.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

* * * * *

(e) * * *

(1) * * *

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 40 to 60		Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*	Feed continuously as sole ration. Do not feed to birds producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses	016592

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(2) * * *

Salinomycin in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50		Quail: For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*	Feed continuously as sole ration. Do not feed to birds producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses	016592

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35. In § 558.625, revise paragraphs (e)(2)(i) and (e)(2)(ix) through (xiii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8 to 10		Beef cattle: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*	Feed continuously as the sole ration to provide 60 to 90 mg/head/day tylosin.	016592 054771 058198 066104

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(ix) 8 to 10	Monensin 10 to 40 plus melengestrol 0.25 to 2.0	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)	Feed continuously as sole ration to heifers at a rate of 0.5 to 2 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into the complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin at feeding into the amount of complete feed consumed by an animal per day. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See §§ 558.342(d) and 558.355(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; melengestrol provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(x) 8 to 10	Monensin 10 to 40 plus ractopamine 8.2 to 24.6	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed	Feed continuously as sole ration to provide 70 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.355(d) and 558.500(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(xi) 8 to 10	Monensin 10 to 40 plus ractopamine, not to exceed 800	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter for the last 28 to 42 days on feed	Feed a minimum of 1.0 lb/head/day ractopamine Type C top dress feed continuously to cattle fed in confinement for slaughter, to provide 70 to 400 mg/head/day ractopamine for the last 28 to 42 days on feed. Feed on top of a ration containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin phosphate, to provide 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. A withdrawal	016592 054771 058198

			time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.355(d) and 558.500(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	
(xii) 8 to 10	Monensin 10 to 40 plus ractopamine 9.8 to 24.6	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter for the last 28 to 42 days on feed	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.355(d) and 558.500(d) of this chapter. Tylosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine as provided by No. 016592, 054771, or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(xiii) 8 to 10	Monensin, 10 to 40 plus ractopamine, 9.8 to 24.6, plus melengestrol, 0.125 to 1 mg/lb	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed	Feed continuously as sole ration to provide 90 to 430 mg/head/day ractopamine and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin for the last 28 to 42 days on feed. Feed melengestrol as a top dress or mixed with a complete ration at the rate of 0.5 to 2.0 pound/head/day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate/head/day (specify one level). A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in §§ 558.342(d), 558.355(d), and 558.500(d) of this chapter. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; ractopamine as provided by No. 016592, 054771, or 058198; melengestrol acetate as provided by No. 016592 or 054771 in § 510.600(c) of this chapter.	016592 054771 058198

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Dated: October 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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